

### **REMARKS**

Favorable reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 115-125, 129, 141-144, 148 and 149 are being examined. Claims 119-125, 129, 141-144, 148 and 149 are rejected under 35 U.S.C. § 112, second paragraph. Claims 119-125, 141-144 and 149 are rejected under 35 U.S.C. § 102. Claims 115-125, 129, 141-144, 148 and 149 have been rejected under 35 U.S.C. § 103. Claims 115, 117-118, 129, 141-144 and 149 have now been amended. Claims 119-125 and 148 have now been cancelled. New claims 184 -186 have now been added.

#### ***Claim Objections***

Claims 115, 117, 118, 119, 129, 141 and 148 are objected to for reciting "Portulaca oleracea" in a non-italicized format. Claims 119 and 148 have now been cancelled, rendering moot Examiner's objection in this case. Italicization of "Portulaca oleracea" has now been effected in the other aforementioned claims.

#### ***35 U.S.C. § 112, second paragraph Rejections***

The Examiner has rejected Claims 119-125, 129, 141-144, 148 and 149 under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the Examiner states the phrase "fraction extract" is unclear, since the claimed composition can only be a fraction or an extract and not both.

The Examiner's rejection is traversed. Claims 119-125 and 148 have been cancelled, rendering moot Examiner's rejection in this case. For the sake of clarity, and in order to expedite prosecution of this case, Applicant has removed the word "fraction" from claims 129, 141-144 and 149.

In view of the above amendments, Applicant believes to have overcome 35 U.S.C. § 112, rejections.

#### ***35 U.S.C. § 102, Rejections***

The Examiner has rejected Claims 119-125, 141-144 and 149 under 35 U.S.C. § 102 as being anticipated by Bae et al (KR 2001004857 A) as evidenced by Kin et al (JP 63208531 A).

The Examiner states that Bae et al teach that *Portulaca oleracea L* may be heated with hot water (a polar fraction extract) or dissolved with ethanol solvent (a polar fraction) extract and thus inherently contain the same chemical components as the instantly claimed composition. The Examiner states that Kin et al teaches water extracts of *Portulaca oleracea L* are effective against diabetes. Further, the Examiner states that Bae does not teach that their disclosed composition is precluded for being effective against diabetes.

The Examiner's rejection is respectfully traversed. Please note that Claims 119-125 have been cancelled.

Applicant wishes to point out to that the pharmaceutical composition of Claim 141 is limited by comprising a therapeutically effective amount for reducing blood glucose levels. Since Bae et al does not teach the use of *Portulaca oleracea L* compositions for lowering blood glucose levels, but rather for use as an antimicrobial or anti cancer agent, Applicant contends that the pharmaceutical compositions of Bae et al do not comprise the same amounts of extract and as such cannot be used to anticipate the presently claimed pharmaceutical composition.

In view of the above comments and claim limitations, Applicant believes to have overcome 35 U.S.C. § 102, rejections.

### ***35 U.S.C. § 103(a), Rejections***

The Examiner has rejected Claims 115-125, 129, 141-144, 148 and 149 have been rejected under 35 U.S.C. § 103 as being unpatentable over Bae et al (KR2001004857) as evidenced by Kin et al (JP 63208531 A).

The Examiner states that Bae et al teach polar extracts of *Portulaca oleracea* (using either water or ethanol) and thus inherently contain the same chemical components as the instantly claimed composition. The Examiner states that Kin et al teaches water extracts of *Portulaca oleracea L* are effective against diabetes. Further, the Examiner states that Bae does not teach that their disclosed composition is precluded for being effective against diabetes.

The Examiner states that Bae et al do not teach an ethanol-water extract with the claimed ratio or a solvent of methanol:ethanol:water in proportions of 1:1:1. However, the Examiner states that it would have been obvious to use the ethanol-water extract since Bae et al teach extracting *Portulaca oleracea L* with water and ethanol, and since ethanol and water are often used in a mixture as a conventional

solvent in the art. Further, the Examiner states that it would have been obvious to add methanol to the mixture, since methanol and ethanol are used interchangeably in the art since they have similar polarities, and adding methanol to the mixture reduces the boiling temperature of the mixture solvent so that the heat labile components would not be altered.

The Examiner's rejection is respectfully traversed. Applicant wishes to point out that extraction using a combination of water and ethanol is superior and synergetic to the use of water or ethanol alone and thus, the resultant composition cannot be obviated using the art of Bae et al. The superiority of the ethanol-water extract is exemplified in the present specification by its outstanding and surprising results - see for example Page 38, lines 24-28:

*"In both groups of Type 2 diabetes patients, a **remarkable** reduction in the level of blood glucose was observed. Diabetic patients whose blood glucose at the start of trial was less than 300 mg/dl maintained normal blood glucose levels after 2 - 3 weeks. Normal blood glucose levels were attained after 4 - 5 weeks in the group of diabetic patients with initial levels that were greater than 300 mg/dl".*

Applicant further wishes to point out that ethanol has different polarity, miscibility and extraction properties as those of methanol, and therefore use of methanol is not obviated by Bae et al.

In addition, Applicant contends that the art of Kin cannot be used in combination with Bae et al to obviate the presently claimed invention since Kin specifically states that only compositions that have been prepared by soaking whole portulaca plants in warm water and then subsequently dried for 60 days or longer can be used to treat diabetes – see page 3 of the translation enclosed herein.

*"The present invention is characterized by soaking whole portulaca plants in warm water and subsequently drying them for 60 days or longer without exposing them to direct sunlight. **Only when portulaca is processed in this manner does it become possible to extract from portulaca an essence that dramatically lowers the blood sugar level of diabetic patients**"*

As such Kin et al teaches away from using an ethanol:water extract or an ethanol:water:methanol extract for lowering blood glucose levels.

New claims 184 and 185 have now been added to further distinguish the presently claimed extracts from those of Bae et al. As clear from the Bae translation,

enclosed herein (Page 13), Bae et al teaches extraction first by placing in hexane and then in other solvents such as ethanol.

*"The portulaca oleracea, which is composed of the above elements, are placed in hexane for 10 hours to remove fat completely and the degreased portulaca oleracea residues are solved in ethyl acetate, chloroform, or ethanol solvents."*

Support for the phrase "extracting components" may be found throughout the instant specification – see for example Page 18, lines 6 and 7.

Support for the phrase "without prior extraction using a non-polar solvent" may be found in the instant specification. The specification teaches different methods of extraction one which includes extraction using polar solvents with prior extraction using non-polar solvents e.g. hexane (See Example 1 of the specification) and another which includes extraction using polar solvents (e.g. a mixture of ethanol:water) without prior extraction using non-polar solvents (See example 2 of the specification – page 38, lines 1-6). Thus, Applicant believes there is adequate support for this claim amendment.

For all the reasons cited above, the *prima facie* case of obviousness is fully rebutted. Unless the Examiner can articulate objective reasons that the arts are combinable and there is motivation to do so, the rejection of the pending claims as obvious must be withdrawn.

In view of the above amendments and remarks it is respectfully submitted that claims 115-118, 129, 141-144, 149 and 184-186 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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**Enclosures:**

- Petition for Extension (Three Months)
- Additional Claims Transmittal Fee
- Translation of Kin et al
- Translation of Bae et al